902 KAR 55:010. Licensing of manufacturers and wholesalers.

RELATES TO: KRS 218A.150(1), 218A.160, 218A.170, 218A.200, 21 C.F.R. 210.1-210.3, 211.1-211.208, 1301.01-1301.93, 1304.01-1304.33

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.150(1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.150, 218A.160 and 218A.170 authorize the Cabinet for Health Services to license manufacturers and wholesalers of controlled substances. This administrative regulation establishes uniform requirements for the licensing of manufacturers and wholesalers.

Section 1. Definitions. (1) "Health care entity" means any organization, or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care.

(2) "Manufacturer" means a person engaged in the commercial manufacture of a controlled substance.

(3) "Wholesale distribution" means distribution of a controlled substance to a person other than a consumer or a patient, and shall not include:

(a) An intracompany sale; or

(b) A distribution by:

1. A charitable organization that meets the criteria established in 26 USC 501(c)(3) to a nonprofit affiliate of the organization to the extent permitted by law;

2. A hospital or health care entity which is a member of a group-purchasing organization to other hospitals or health care entities that are members of the organization; or

3. A pharmacy that is exempt pursuant to 902 KAR 55:060.

(4) "Wholesaler" means a person who is engaged in the wholesale distribution of a controlled substance, including:

(a) Own-label distributor;

(b) Private-label distributor;

(c) Jobber;

(d) Broker;

(e) Warehouse, including a manufacturers' or distributors' warehouse, chain drug warehouse, or wholesale drug warehouse;

(f) Independent wholesale drug trader; and

(g) Pharmacy that conducts wholesale distributions.

Section 2. License Required and Exceptions. (1) A separate license shall be required for each location from which a manufacturer or wholesaler makes a wholesale distribution of a controlled substance into the Commonwealth.

(2) If a location has more than one (1) registration with the Drug Enforcement Administration, each registrant that distributes in the Commonwealth shall obtain a separate license.

(3) A license to distribute controlled substances shall not be transferred or assigned.

(4) A license shall not be required for an agent or employee of a licensee if the agent or employee is acting in the usual course of business or employment.

Section 3. Application for License or Renewal. (1) An application for a manufacturer's or wholesaler's license shall be submitted to the Cabinet for Health Services on "Application for New License as Manufacturer or Wholesaler of Controlled Substances", DCB-10 form, and include the following information:

(a) The name, business address and telephone number of the prospective licensee;

(b) All trade or business names used by the licensee;

(c) Name, address, and telephone number of each contact person for controlled substance handling, storage, and recordkeeping;

(2) An application for a manufacturer's or wholesaler's license shall include the following information about the ownership of the business:

(a) The type of ownership of operation;

(b) If an individual or sole proprietorship, the full name of the individual or proprietor and the name of the business entity;

(c) If a partnership, the name and address of each partner and the name of the partnership;

(d) If a limited liability company, the name and address of each manager and member; and

(e) If a corporation, the name and title of each corporate officer and director, the corporate names, and the names of the state of incorporation.

(3) A description of the business, the physical facilities, and the type security provided.

(4) A change in the information required by subsection (1), (2), or (3) shall be submitted to the cabinet:

(a) Within thirty (30) days from the date of the change, or at the time of license renewal, whichever occurs first; and

(b) On a "License Update Manufacturer or Wholesaler of Controlled Substances", DCB-11 or an "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances", DCB-12.

Section 4. Qualifications for License or Renewal. (1) The cabinet shall consider the following factors in reviewing the qualifications of an applicant to engage in the manufacture or wholesale distribution of controlled substances:

(a) A conviction of the applicant or its managing officers under any federal, state, or local law relating to controlled substances;

(b) A felony conviction of the applicant or its managing officers;

(c) An applicant's history with state or federal regulatory agencies as related to the manufacture or distribution of controlled substances;

(d) The furnishing of false or fraudulent information in connection with an application for a license from a federal, state or local government agency;

(e) Suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of controlled substances;

(f) Compliance with licensing requirements under previously granted licenses, if any;

(g) Compliance with requirements to maintain or make available to the cabinet or to federal, state, or local law enforcement officials those records required by KRS 218A.200;

(h) The criteria listed in KRS 218A.160; and

(i) Violations of applicable federal law, rule or regulation or state law, or administrative regulation governing a controlled substance that relates to Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs in 21 CFR 210.1 to 210.3 or Current Good Manufacturing Practice for Finished Pharmaceuticals in 21 CFR 211.1 to 211.208, adopted by the U.S. Food and Drug Administration.

(2) A license shall be renewed if the cabinet finds that the applicant:

(a) Qualifies for a license pursuant to subsection (1) of this section;

(b) Complies with Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances 21 CFR 1301.01 through 1301.93, adopted by the Drug Enforcement Administration;

(c) Complies with Records and Reports of Registrants 21 CFR 1304.01 through 1304.33, adopted by the U.S. Drug Enforcement Administration;

(d) Complies with KRS 315.036 and 201 KAR 2:105; and

(e) Complies with KRS 218A.200.

(3) A manufacturer or wholesaler not located within the Commonwealth of Kentucky may obtain a license or license renewal on the basis of reciprocity if:

(a) The out-of-state manufacturer or wholesaler possesses a valid license granted by another state and the legal standards for licensure in the other state are no less stringent than the standards established by this administrative regulation;

(b) The out-of-state manufacturer or wholesaler is currently registered with the U.S. Drug Enforcement Administration; and

(c) The state in which it is licensed extends reciprocity to manufacturers and distributors licensed by Kentucky.

(4) All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

Section 5. License Fees; Renewals. (1) An application for a license under the provisions of this administrative regulation shall be submitted to the Cabinet for Health Services on an "Application for New License as Manufacturer or Wholesaler of Controlled Substances" DCB-10 form and shall be accompanied by a license fee of $240.

(2) An application to renew a license shall be submitted to the Cabinet for Health Services on an "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances", DCB-12 form, and shall be accompanied by a renewal fee of $175.

Section 6. Recordkeeping. (1) Records shall be maintained in accordance with KRS 218A.200 and with 21 CFR 1304.01 to 1304.33, adopted by the U.S. Drug Enforcement Administration.

(2) Records or copies of records that relate to distributions within the Commonwealth shall be made available to the cabinet upon request.

Section 7. License Termination, Lapse, Suspension or Revocation. (1) A license issued pursuant to this administrative regulation shall be suspended or revoked for cause.

(2) A license shall terminate if the licensee dies or ceases legal existence.

(3) A license shall lapse if the renewal application and renewal fee have not been filed with the cabinet prior to June 30 of each year.

(4) A lapsed license shall be void and an application for a new license shall be required.

(5) All administrative hearings shall be conducted in accordance with 902 KAR 1:400.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for New License as Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-10;

(b) "License Update Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-11;

(c) "Application for Renewal License as Manufacturer or Wholesaler of Controlled Substances (8/98)", DCB-12.

(2) This material may be inspected, copied, or obtained at the Cabinet for Health Services, Department for Public Health, Drug Control and Professional Practices, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. - 4:30 p.m. (Recodified from 901 KAR 1:010, 4-14-82; Am. 8 Ky.R. 1181; 1601; eff. 6-25-82; 11 Ky.R. 1673; eff. 6-4-85; 14 Ky.R. 2084; eff. 6-22-88; 17 Ky.R. 136; eff. 9-13-90; 22 Ky.R. 2480; 8-1-96; 25 Ky.R. 625; 1628; eff. 1-19-99.)